DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER
NWE-07-04W

VIA FEDERAL EXPRESS

November 25, 2003

Mr. Richard Chapman
President
North Country Dairy Supply, Inc.
P.O. Box 26
West Rutland, VT 05777

Dear Mr. Chapman:

An inspection of your facility located at 919 Claredon Road, West Rutland, VT, conducted by a Food and Drug Administration (FDA) investigator on July 28, 2003 and August 1, 2003, found significant deviations from FDA's regulations establishing current good manufacturing practices (cGMPs) for finished pharmaceuticals, Title 21, Code of Federal Regulations (C.F.R.) Part 211. Such deviations cause the cow teat dips manufactured by your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(a)(2)(B). They are also misbranded under Section 502(o) of the Act.

Under Section 201(g)(1)(B) of the Act, drugs are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." Because your cow teat dips are intended for use in controlling mastitis in cows, they are a drug under the Act.

Under Section 501(a)(2)(B) of the Act, if the methods used in, or the facilities or controls used for, a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice, it is deemed adulterated. Our investigator found the following deviations from the cGMPs for finished pharmaceuticals:

1. You have failed to establish written responsibilities and procedures applicable to a quality control unit, as required by 21 C.F.R. 211.22(d).

2. You have failed to make an appropriate laboratory determination of satisfactory conformance to final specifications for the [redacted] teat dip drug products as required by 21 C.F.R. 211.165(a).

3. You fail to maintain and follow written procedures for the sampling and testing of your [redacted] teat dip drug products, including the method of sampling and the number of units per batch to be tested. 21 C.F.R. 211.165(c).

4. You failed to establish and follow written procedures describing in sufficient detail the controls employed for the issuance of labeling for your teat dip drug products as required by 21 C.F.R. 211.125(f).

5. You have failed to maintain written records of the calibration checks of automatic, mechanical or electronic equipment as required by 21 C.F.R. 211.68(a). You do not have any documentation that the floor scale used to weigh all ingredients used in the manufacturing of your teat dip drug products has been calibrated. You have no records to establish the accuracy and repeatability of the scale for its use to weigh the drug product ingredients used in the manufacturing process.

6. You have failed to store the drug product reserve samples in an immediate container-closure system that is the same as or has essentially the same characteristics as the marketed products as required by 21 C.F.R. 211.170(b).

7. The buildings used in the manufacture, processing, packing, and holding of your drug products are not of a suitable size to facilitate cleaning, maintenance , and proper operations as required by 21 C.F.R. 211.42(a).

A review of our files also shows that your veterinary drug manufacturing establishment located 919 Claredon Road, West Rutland, VT, is not registered and has not drug listed with the FDA, as required by Section 510 of the Act. This failure constitutes a continued violation of the Act. All drugs manufactured, prepared, propagated, compounded, or processed by your firm are misbranded within the meaning of Section 502(o) of the Act because your firm is not registered and has not drug listed as required by Section 510 of the Act.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drug products, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you are taking to correct the deficiencies and to assure that such violations will not recur. If you cannot complete all corrections before you respond, explain the reason for the delay and a deadline by which you will correct any remaining deficiencies. Correspondence concerning this matter should be directed to the Food and Drug Administration, One Main Street, 4th floor, Stoneham, MA 02108, Attention Ann Simoneau, Compliance Officer.

Sincerely yours,

Gail T. Costello
District Director